# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

JULIE DELANEY and WILLIAM P. DELANEY

Plaintiffs,

v.

CIVIL ACTION No. 05-CV-10241 (MLW)

ELI LILLY AND COMPANY,

Defendant.

# DEFENDANT ELI LILLY AND COMPANY'S CONSENT MOTION FOR LEAVE TO FILE REPLY BRIEF

Defendant Eli Lilly and Company ("Lilly") moves this Court for leave to file a Reply in support of its Motion to Strike the Statement of Harold Sparr (Docket No. 45, Ex. 11). Lilly's Reply is filed concurrently herewith.

As grounds for this motion, Lilly states that the Reply is necessary to address arguments regarding Mr. Sparr's statement raised in Plaintiff's Opposition. Lilly believes the Reply will be of assistance to the Court in resolving the issues raised by Lilly's Motion to Strike.

WHEREFORE, Lilly requests the Court grant this motion for leave to file the Reply brief filed concurrently herewith.

Respectfully submitted,

ELI LILLY AND COMPANY By its attorneys,

/s/ Brian L. Henninger
James J. Dillon (BBO # 124660)

<sup>&</sup>lt;sup>1</sup> Because Plaintiffs relied on two separate affidavits from Mr. Sparr in their opposition to Lilly's motion for summary judgment (Docket No. 45 at Exs. 7, 11), Lilly has filed separate motions titled Motion to Strike the Affidavit of Harold Sparr (Docket No. 49) and Motion to Strike the Statement of Harold Sparr (Docket No. 48). The present Motion for Leave to File Reply Brief relates to the latter motion.

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Dated: December 19, 2006

#### LOCAL RULE 7.1(A)(2) CONFERRAL CERTIFICATION

I, Ericka Harper Snyder, certify that on December 19, 2006, I conferred with Plaintiffs' counsel regarding Lilly's Motion for Leave to File a Reply Brief. Plaintiffs' counsel consented to the Motion.

/s/ Ericka Harper Snyder

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ELI LILLY AND COMPANY,

Defendant.

# ELI LILLY AND COMPANY'S [PROPOSED] REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE STATEMENT OF HAROLD SPARR (Docket No. 45, Ex. 11)

In their Opposition to Defendant Eli Lilly's Motion to Strike the Statement of Harold Sparr ("Plaintiffs' Opposition" at Docket No. 52), Plaintiffs argue that Mr. Sparr's "expert" testimony regarding Massachusetts DES market share should not be excluded on summary judgment. Plaintiffs rely on Mr. Sparr notwithstanding his deposition testimony which disclosed that he had no basis for the sweeping statements made and that his "expert" work was only as an employee for Plaintiffs' counsel. Indeed, Mr. Sparr's statement is based on (1) his limited experience in retail pharmacy and related professional associations, (2) a survey study commissioned by Plaintiffs' counsel, and (3) interviews with pharmacists at the direction of Plaintiffs' counsel. Yet Mr. Sparr never worked at the pharmacy where Plaintiff's mother allegedly obtained DES (Hingham Pharmacy), nor did he work in any other pharmacies in Hingham, Massachusetts. His "market survey" suffers from many flaws, not the least of which were inappropriate selection criteria and his failure to verify the accuracy of any responses. His

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<sup>&</sup>lt;sup>1</sup> Lilly filed two separate motions to strike concerning Mr. Sparr because Plaintiffs relied on two separate affidavits from him in their opposition to Lilly's motion for summary judgment (Docket No. 45, Exs. 7 and 11). The present motion addresses Mr. Sparr's statement at Docket No. 45, Ex. 11 concerning the DES market in Massachusetts and his "market survey."

interviews with pharmacists were directed by Plaintiff's counsel for the stated goal of determining whether the pharmacist recalled dispensing Lilly's DES. On its face, Mr. Sparr's "expert" testimony does not rise the level of reliability and relevance required by F.R.E. 702 and Fed. R. Civ. P. 56(e), and must be excluded.

# A. PLAINTIFF'S AUTHORITIES RECOGNIZE THAT "EXPERT" TESTIMONY CAN BE EXCLUDED ON SUMMARY JUDGMENT

Plaintiffs argue in their Opposition that the Court cannot exclude "expert" testimony on summary judgment without a Fed. R. Evid. 104(a) hearing unless the defects are obvious on the face of the proffer. *See* Plaintiff's Opposition, at 3-4. The authorities cited by Plaintiffs in support of a Rule 104(a) hearing make room for exclusion of expert testimony that is defective on its face, *Cortez-Irizarry v. Corporacion Insular*, 111 F.3d 184, 188 (1<sup>st</sup> Cir. 1997), or that is irresponsible and irrelevant, *Tuf Racing Prods., Inc. v. American Suzuki Motor Corp.*, 223 F.3d 585, 591 (7<sup>th</sup> Cir. 2000). Lilly's Motion to Strike is premised on the argument that Mr. Sparr's "expertise" is facially defective because it is based on a limited personal experience not relevant to the issue in this case and a market survey that shed no light on the stocking and dispensing practices of a particular pharmacy in Hingham, Massachusetts in 1969 and 1970. Mr. Sparr's testimony on the Massachusetts DES market is mere speculation and has no relevance to this case. *See, e.g., Hernandez v. NATMAR, Inc.* 1998 WL 37497 at \*9-10 slip op. (D.D.C. Jan. 22, 1998) (disregarding Plaintiff's expert report on summary judgment because it was based on pure speculation).

### B. MR. SPARR'S PERSONAL EXPERIENCE AS A MASSACHUSETTS PHARMACIST IS IRRELEVANT

As detailed in Mr. Sparr's deposition (Docket No. 51, Ex. 1) and in Lilly's related motion to strike his "expert" affidavit concerning the prevalence of Lilly's DES in Hingham (Docket No. 49), Mr. Sparr never worked at the pharmacy where Ms. Delaney's mother allegedly

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obtained DES, nor did he work in any other pharmacies located in Hingham. Indeed, Mr. Sparr has practiced in only four Massachusetts pharmacies. (Docket No. 45, Ex. 7, at ¶ 3) Having no experience with any pharmacies in Hingham, Mr. Sparr's testimony with respect to the dispensing practices at the Hingham Pharmacy is pure speculation.

# C. MR. SPARR'S PERSONAL EXPERIENCE AS A MEMBER OF THE MASSACHUSETTS PHARMACY COMMUNITY IS IRRELEVANT

Recognizing that Mr. Sparr has no personal knowledge of the DES dispensed at the Hingham Pharmacy or in Hingham generally, Plaintiffs cite his other experience in the Massachusetts pharmacy community as a basis for his "expertise." *See* Plaintiff's Opposition at 6, 15-16. A brief look at some of these activities reveals that they impart no expertise to Mr. Sparr that is relevant to this case.

- President, Massachusetts Board of Registration of Pharmacy -- Mr. Sparr was not appointed or elected to this position until 1995, 25 years after Ms. Delaney's alleged exposure to DES.
- President, Massachusetts College of Pharmacy and Health Services
   Alumni Association -- Mr. Sparr was not appointed or elected to this
   position until 1998, 28 years after Ms. Delaney's alleged exposure to DES.
- Reviewing and Personally Observing Massachusetts Retail Drug Store Practices And The DES Environment, 1954-1971 -- Mr. Sparr admitted at his deposition that the only retail drug store practices he observed were those of the stores in which he worked, none of which were located in Hingham. *See* Sparr Tr. at 116-17 (Docket No. 48, Ex. 1).
- Visited Hundreds of Boston-Area Pharmacies; Talked to Hundreds of Pharmacists -- Mr. Sparr conducted these interviews and visits sometime after 2003 while he was working for Plaintiff's counsel. Mr. Sparr understood that the goal of the interview was to confirm that the pharmacist remembered dispensing Lilly. See id. at 15-19, 55-57, 84-90. Indeed, Mr. Sparr told pharmacists that he wanted to speak with them in connection with "current lawsuits [involving] the Liability Insurance Company who insured Eli Lilly & Co." See Letter from Harold Sparr to George Friedman, R.Ph., dated Dec. 5, 2003 (Docket No. 48, Ex. 6). Mr. Sparr made no effort to check the memories of the pharmacists with which he spoke or to organize notes of his conversations. See Sparr Tr. at 15-19,

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55-57, 84-90 (Docket No. 48, Ex. 1). *See also* Reference Manual on Scientific Evidence (2d ed. 2000), at 253 ("[I]nterviewers should record verbatim both what the respondent says and what the interviewer says in the attempt to get clarification. Failure to record every party of the exchange in the order in which it occurs raises questions about the reliability of the survey, because neither the court nor the opposing party can evaluate whether the probe affected the views expressed by the respondent.").

• Teacher, Massachusetts College of Pharmacy and Northeastern University -- Mr. Sparr's role teaching and supervising students in hospital pharmacies after 1970 did not involve seeing or filling any prescriptions for DES for the use in pregnancy. *See* Sparr Tr. at 118-19 (Docket No. 48, Ex. 1).

There is no reason to believe that Mr. Sparr learned anything relevant to the specific facts of *this case* from the activities above. For all these reasons, Mr. Sparr's membership in the Massachusetts pharmacy community does not qualify him as an expert on DES market in Massachusetts in 1969-70.

# D. MR. SPARR'S SURVEY METHODS ARE NOT RELIABLE AND HAVE NO RELEVANCE TO THE FACTS OF THIS CASE.

In order for a witness to offer an expert opinion, he must be "qualified as an expert by knowledge, skill, experience, training, or education" <u>and</u> his testimony must: 1) be based upon sufficient facts or data; 2) be the product of reliable principles and methods; and 3) apply the principles and methods <u>reliably</u> to the facts of the case. F.R.E. 702. While Plaintiffs' proffer fails in all of these areas, Lilly wishes to focus the Court's attention on several facts which

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<sup>&</sup>lt;sup>2</sup> Lilly's Motion to Strike fully sets forth the facts and the law that support the conclusion that Mr. Sparr is not qualified by "knowledge, skill, experience, training, or education" to offer an expert opinion on the market share of Lilly's DES in Massachusetts from 1955-1971. *See* Lilly's Motion to Strike at 2-12 (Docket No. 48). Lilly's Motion to Strike also details the insufficiencies in the facts and data upon which Mr. Sparr bases his opinion and on the unreliability of Mr. Sparr's principles and methods. *See id*.

underscore the necessary conclusion that Mr. Sparr has not and cannot apply his survey methods reliably to this case.<sup>3</sup>

First, Mr. Sparr's "market survey" was limited to pharmacists (1) first licensed in Massachusetts from 1963 to 1967, and (2) still practicing in 2004. Not only does this selection serve no scientific purpose, it is unreliable for determining a proper sample of pharmacists. Only those pharmacists who had been practicing for less than six years in 1969-70 and who were still practicing in 2004 were allowed to complete the survey, thereby excluding pharmacists who had more experience (and presumably more responsibility) in their respective pharmacies, as well as pharmacists who have since retired or moved. Indeed, Mr. Sparr acknowledged that only 225 pharmacists participated in his survey out of approximately 4500-5000 pharmacists practicing between 1963 and 1967. Sparr Tr. at 156-57 (Docket No. 48, Ex. 1).

Second, Mr. Sparr's survey does not take into account the reliability of the pharmacists' memories of a drug dispensed more than 35 years ago. As one respondent aptly noted, "I believe that we only stocked Lilly's brand but I could be mistaken. That was a long time ago!" August 26, 2004 Letter from Hannelore Vanderschmidt to Harold Sparr (Docket No. 53, Ex. 2). Yet when asked whether he attempted to verify the accuracy of any of the respondents' memories about the DES dispensed in their stores, Mr. Sparr responded "No. How could I?" Sparr Tr. at 97 (Docket No. 48, Ex. 1).

Third, the survey did not ask what brand of DES each pharmacy stocked, but rather asked what brand would have been "primarily dispensed." Sparr Survey (Docket No. 48, Ex. 4)

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<sup>&</sup>lt;sup>3</sup> Plaintiffs cite cases for the proposition that whether an expert's methodology is reliable "goes only to the weight, and not the admissibility, of the surveys." Plaintiffs' Opposition at 13-14 (citing Southland Sod Farms v. Stover Seed Co., 108 F.3d 1134 (9th Cir. 1997) and E&J Gallo Winery v. Gallo Cattle Co., 967 F.2d 1280 (9th Cir. 1992)). However, this statement must be read in context. The court stated that "as long as [the surveys] are conducted according to accepted principles ... a jury should be able to determine whether asserted technical deficiencies undermine a survey's probative value." Southland Sod at 1143, n.8. Here, Plaintiffs have utterly failed to demonstrate that Mr. Sparr's survey was conducted according to accepted principles.

(emphasis in original). The respondents were not encouraged to list all brands of diethylstilbestrol available in their respective pharmacies, much less given clear instructions for what "primarily dispensed" means. "When unclear questions are included in a survey, they may threaten the validity of the survey by systematically distorting responses if respondents are misled in a particular direction, or by inflating random error if respondents guess because they do not understand the question." Reference Manual on Scientific Evidence (2d ed. 2000), at 248.

Finally, Plaintiffs admit that there may have been an "oversight" in allowing the survey responses to include data for DES prescribed for all ailments, not just to prevent accidents of pregnancy. Plaintiff's Opposition at 12. There is no evidence as to what percentage of DES prescriptions were for ailments other than accidents of pregnancy. Thus, Mr. Sparr's survey cannot reliably say anything about the market share applicable to this case - the DES market in 1969 and 1970 in Hingham, Massachusetts prescribed for accidents of pregnancy.

# E. PLAINTIFFS' COUNSEL'S AFFIDAVIT DOES NOT CURE THE FLAWS IN MR. SPARR'S PROFFERED TESTIMONY

Plaintiffs' counsel's affidavit fails to cure the deficiencies in Mr. Sparr's expertise or methodology. To the contrary, Mr. Levine confirms Lilly's point that "[f]requently, identification evidence points to non-Lilly defendants." Affidavit of Aaron M. Levine, Esquire Regarding Identification ("Levine Aff."), dated Nov. 29, 2006, at ¶ 13 (Docket No. 53, Ex. 4). While Mr. Levine denies involvement in Mr. Sparr's work with Dr. Vanderschmidt aside from their initial discussion over survey criteria, he does not deny that the goal of the survey was to identify Lilly as the prevalent DES manufacturer, nor does he deny that he directed Mr. Sparr to search for and interview pharmacists with the specific goal of identifying Lilly. *See*, *e.g.*, Sparr Tr. at 57 ("Q. Did you understand when you were interviewing those pharmacists that the goal was to see if the pharmacist would remember Eli Lilly and Company as the drug that they had?

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A. Yes.") (Docket No. 48, Ex. 1); Letter from Harold Sparr to George Friedman, R.Ph., dated Dec. 5, 2003 ("The current lawsuits involve the Liability Insurance Company who insured Eli Lilly & Co.") (Docket No. 48, Ex. 6).

Mr. Levine also acknowledges in his affidavit that "often, the identification evidence is so deficient that the cases are dismissed or rejected.... For example, if the mother of the plaintiff is dead or cannot remember what pill she took, and if there are no pharmacy records or live pharmacists." Levine Aff. at ¶ 14 (Docket No. 53, Ex. 4). That is the circumstance here. Ms. Delaney's mother does not know the manufacturer of the pill she took. For the reasons discussed in Lilly's Memorandum In Support Of Its Motion For Summary Judgment, her description of a white, cross-scored pill does not sustain Plaintiff's burden of identifying Lilly. There also are no pharmacy records or live pharmacists from the relevant pharmacy. Accordingly, this case is one that should be rejected.

### **CONCLUSION**

For the foregoing reasons, Lilly respectfully requests that the Court strike Mr. Sparr's statement from the record. Lilly submits that Mr. Sparr's statement is incompetent for lack of personal knowledge, unreliable, and will not assist the Court in understanding the evidence relevant to this case, thus warranting its exclusion pursuant to Federal Rules of Evidence 602 and 702.

Respectfully submitted,

ELI LILLY AND COMPANY By its attorneys,

/s/ Brian L. Henninger\_ James J. Dillon (BBO # 124660) Brian L. Henninger (BBO # 657926) Foley Hoag LLP 155 Seaport Boulevard World Trade Center West

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Dated December 19, 2006

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